

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Group Art Unit: 3772

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Examiner: Brandon Jackson

Serial Number: 10/714,694

Filed: November 17, 2003.

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FOR: Cheek Path Airway And Cheek Pouch Anchor

1 SUBSTITUTE SPECIFICATION (clean version)

2

3 Commissioner of Patents and Trademarks

4 Washington, D.C. 20231

5

6 Sir:

7 In response to the Office Action mailed February 21, 2007, I am appending a

8 clean version of the SUBSTITUTE SPECIFICATION WITH AMENDMENTS AND

9 AMENDED ABSTRACT, RESPONSIVE TO OFFICE ACTION MAILED FEB. 21, 2007.

SUBSTITUTE SPECIFICATION

TITLE OF INVENTION:

CHEEK PATH AIRWAY AND CHEEK POUCH ANCHOR.

CROSS REFERENCE TO RELATED APPLICATIONS.

[0001] There are no related applications.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR
DEVELOPMENT.

[0002] No federally-sponsored research and development is involved.

THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.

[0003] Not applicable.

BACKGROUND OF THE INVENTION.

[0004] 1. Field of the Invention.

[0005] The field of the invention is oral conduits for fluids, including oral airways.

[0006] 2. Background Art.

[0007] Nasal Breathing Restrictions.

[0008] Some persons at times breathe nasally during sleep, with the lips and jaws closed, thereby eliminating the mouth as an effective airway. Closed-mouth, nasal breathing through restricted nasal air ways reduces ventilation volume and can impair breathing and sleep. Restrictions in the nasal airway path may significantly contribute to breathing insufficiency during sleep in some persons who breathe nasally with lips closed. Scientific and medical experts have reported (or hypothesized) a variety of contributing and causal factors other than nasal airway restriction for hypopnea and apnea, such as sagging of the base of the tongue, and possibly the lower jaw, towards the throat, resulting in restriction or blockage of the throat air way. Nasal restrictions may contribute to snoring and to sleep apnea.

[0009] Jaw and Tongue Control Devices.

[0010] A variety of devices has been developed and patented by others to mechanically control a user's jaw and tongue positions to minimize sagging of tongue and mandible towards the user's throat airway. Some include oral airways. Others are designed to function during closed-mouth, nasal breathing.

1 [0011] It is an objective of the instant cheek airway invention that it be capable of
2 placement and use in combination with a wide variety of exiting jaw- and tongue-
3 control devices, though perhaps with some modification of such devices.

4 [0012] Tongue-control Devices.

5 [0013] A non-exhaustive list of examples of tongue-control devices that incorporate
6 airways or employ positive or negative air pressure is:

7 [0014] Alvarez, et al., U.S. Patent No. 5,465,734 (1995); Hart, U.S. Patent No.
8 5,957,133 (1999); Karell, U.S. Pat. No. 6,408,851 B1, discloses a tongue-fastening
9 device having airway 40 and two or more internal airway openings 42 which, as
10 depicted in Karell's figures 3 and 5, pass between the teeth. Kulick, Pub. No.: US
11 2002/0139375 A1 holds the tongue forward by suction, uses bite blocks 2 to prevent
12 biting the tongue and support air passages 4 into the oral cavity. Nelson, U.S. Pat.
13 6,244,865 B1, discloses a tongue positioning device which includes a hollow
14 passageway 20 in the mouthpiece for flow of breathing gasses into the mouth.

15 [0015] Mouthpieces and Lip-Passing Tubes.

16 [0016] There exists an enormous variety of mouthpieces and other devices for
17 delivery of gasses past the user's lips into the user's mouth. Examples include
18 snorkels and SCUBA (Self-Contained Underwater Breathing Apparatus) mouthpieces,
19 as well as tubes, cannulae and ventilators used in medicine, surgery, anaesthesia,
20 orthodontics, and sports. There also are numerous devices designed to ameliorate
21 some aspect of nasal congestion, snoring, hypopnea and apnea. Some airway
22 devices simply provide conduits to external air at ambient pressure, whereas others
23 are designed to deliver gasses at modified pressures. Examples of the latter are
24 CPAP (Continuous Positive Airway Pressure) and BiPAP (Bi-level Positive Airway
25 Pressure) machines.

26 [0017] Many existing oral airways pass between a user's maxillary and mandibular
27 teeth, requiring bite blocks or other devices to prevent crushing of the airway between
28 the teeth and thus restricting the user's jaw motion.

29 [0018] Devices Using Portions of the Cheek Pathway.

30 [0019] Nelson, in a series of U.S. Patents No. 4,170,230, (1979), 4,261,354 (1981),
31 4,262,666 (1981) and 4,289,127 (1981), discloses several different versions of hollow
32 tubes which traverse portions of a user's cheek pathway. Nelson's devices are

1 designed for stand-alone cheek-side positioning; that is, they are not anchored to
2 teeth-engaging or palate-engaging dental devices. Nelson does not disclose any
3 structure curving around a user's rear-tooth corner, or passing into or through a user's
4 rear-jaw gap, or extending from the user's rear-jaw gap over the user's tongue into
5 airspace in a user's rear-mouth cavity. Nelson describes and depicts his curved tube
6 as open-ended, with at least one opening internal to the user's mouth, and having a
7 length to insure that there will be an air flow opening approximate the molars at the
8 rear of the user's mouth. See, for example, Nelson, U.S. Patent 4,170,230, abstract;
9 column 1:25 - 38; column 2:55 - 67; column 3:19 - 35; column 4: 5 - 14; claims 1 and
10 6; and figs. 1, 2, 3, 5 and 7. Nelson's disclosure states that the air flow opening(s) of
11 Nelson's tube "pass the air from the tube to the rear of the mouth and upper trachea."
12 Since Nelson does not disclose any tube structure dorsal of the user's molars, Nelson
13 leaves a reader to guess the path which air traverses after exiting Nelson's tube
14 "approximate the molars." Nelson, U.S. Patent No. 4,170,230, column 1, lines 44 - 47;
15 column 4, lines 5 - 13; and abstract.

16 [0020] Nelson's patents, and especially U.S. Patent No. 4,289,127 (1981), also
17 disclose various cheek-side stabilizing devices including fin-like, wire-like and rod
18 devices. Nelson describes his cheek-side stabilizing devices as rigid or flexible or
19 malleable, but does not describe them as resilient or spring-like.

20 [0021] Pope and Hawkins, U.S. Patent 4,553,549, disclose a "pressure equalization
21 conduit" attached to an orthopedic/orthodontic appliance for treating neuromuscular
22 imbalance which is positioned "so that the tube extends along the outside surface of
23 the teeth around the posterior of the teeth to the position which is in communication
24 with the pharyngeal cavity." Pope, et al., U.S. Patent 4,553,549, specification col.
25 3:10-20 and claim 13. (Pope's "posterior" presumably corresponds to dorsal.) In
26 contrast with Nelson's cheek-side tubes, the pressure equalization conduit of Pope, et
27 al., is not disclosed as a self-contained device designed to stand alone in a cheek
28 pathway. Rather, the Pope conduit is positioned by wire holders that are embedded in
29 the teeth- and palate-engaging elements of the Pope orthopedic/orthodontic device.
30 Pope et al. U.S. Patent 4,553,549, col. 5:60-68. At least one version of the Pope
31 conduit is disclosed and is explicitly claimed as having "inside diameter of from about 2
32 to 3 mm." Pope, Specification, 3:30-40 and claim 16. However, Pope, et al. do not

1 state limiting diameters.

2 BRIEF SUMMARY OF THE INVENTION.

3 [0022] This application discloses a cheek path airway and a cheek pouch anchor. In
4 a preferred version, they are combined with each other, but each also could be used
5 alone or in combination with other prior art devices. Such other prior art devices
6 include jaw control and tongue control devices.

7 [0023] Summary of Cheek Path Airway Invention. The cheek path airway is a hollow
8 tube or channel configured, or adjustable, to act as a conduit for air or other fluids
9 along a user's "cheek pathway." A user's "cheek pathway" is defined more precisely
10 below.

11 [0024] The cheek path airway bypasses nasal airways and provides oral air flow
12 supplemental to nasal flow, even though the user's lips, teeth and jaws are otherwise
13 closed. Thus, the cheek path airway can provide supplemental air volumes to mitigate
14 breathing impairment caused by restriction of a user's nasal airways without a user
15 having to switch to open-mouth breathing.

16 [0025] The cheek path airway's curve from the cheek-side to the dorsal side of a
17 user's rear-most teeth helps constrain rotational and translational motions of the
18 airway tube in a user's mouth. When a user's jaws are opened the cheek path airway
19 alone (without the cheek pocket anchor) remains somewhat vulnerable to rotating or
20 sliding between the biting surfaces of a user's teeth. The airway can be built to
21 mitigate such motions by using a relatively stiff (or stiffly flexible) curve through the
22 user's rear-jaw gap, and by forming (or flexing) the tongue portion of the airway to
23 conform relatively stiffly to the side and roof of the user's rear-mouth cavity, while more
24 rigid portions of the airway extend along the inner wall of a user's cheek and between
25 a user's lips.

26 [0026] The cheek path airway can be made flexible or moldable at strategic positions
27 along its longitudinal axis so that the action of the user's tongue and jaws will press the
28 airway into locations of lesser interference with movements of the user's tongue and
29 rear-jaw gap, thus achieving better fit and stability.

30 [0027] External extensions of the cheek path airway, which curve about the outside
31 corner of a user's mouth and traverse along the user's external cheek wall, can be
32 employed to further constrain the airway in a cheek pathway. Stability can be further

1 improved by an external extension which folds about a user's ear.

2 [0028] A dual cheek path airway, which traverses the two cheek pathways on either
3 side of a user's mouth, can further increase stability as well as increasing air flow
4 volume and providing redundant conduits.

5 [0029] More positive control over destabilizing motions of a cheek path airway can
6 be achieved by combining the cheek path airway with a cheek pouch anchor.

7 [0030] Summary of Cheek Pouch Anchor Invention. The cheek pouch anchor is a
8 spring element which is adapted to be placed within a user's "cheek pouch," an area
9 which lies between the inner wall of a user's cheek and such user's gums and teeth as
10 more precisely defined elsewhere in this disclosure. The cheek pouch anchor of the
11 instant invention can expand and compress in a resilient or spring-like manner within a
12 user's cheek pouch as a user opens and closes the user's jaws. A cheek pouch
13 anchor can better maintain a cheek path airway's positioning while avoiding the more-
14 mobile ventral portions of a user's tongue, avoiding the biting surfaces of the user's
15 teeth, resisting expulsion from the user's mouth, and mitigating risks of choking and
16 gagging.

17 [0031] The cheek pouch anchor invention is capable of receiving joinder to a work
18 piece that is to be positioned at least partially within such user's cheek pouch. The
19 cheek path airway is one type of work piece that can be joined to the cheek pouch
20 anchor.

21 [0032] It is conceived that the cheek pouch anchor could be impregnated or coated
22 with substances that are intended to be released over time within a user's mouth, or it
23 could carry and position containers and other devices at least partially within a user's
24 cheek pouch.

25 [0033] Summary of Combination of Cheek Path Airway and Cheek Pouch Anchor
26 Inventions.

27 [0034] The combination of the cheek path airway and the cheek pouch anchor
28 provides additional constraints upon rotations and translations of the cheek path
29 airway, beyond the constraints built into the cheek path airway itself, which render the
30 combination more suitable for use during sleep.

31 [0035] Summary of Combination of Cheek Path Airway With Existing Jaw- and
32 Tongue-Control Devices. The cheek path airway can be used (with or without the

1 cheek pouch anchor) in combination with a mandibular jaw control device that restricts
2 sagging of a user's mandible toward such user's throat airway during sleep for the
3 purpose of mitigating throat airway impairment and sleep apnea. It is conceived that
4 the cheek path airway also could be used in combination with many other dental, jaw,
5 and tongue control devices. The cheek path airway can functionally leverage itself
6 against a dental device installed in a user's mouth so as to improve the airway's
7 stability within the cheek pathway, but without substantial impairment of the function of
8 such dental device, so that the combination functions cooperatively to mitigate a user's
9 breathing problems.

10 [0036] Some Special Anatomical Definitions. The following definitions have been
11 created for the purposes of this disclosure and the claims:

12 [0037] "User" means the creature using a device, generally a human, though devices
13 in principle could be used by creatures other than humans.

14 [0038] "User's anterior-posterior axis" means head to foot for a human user, head to
15 tail for other creatures. Sometimes also called a "vertical" axis when a human is
16 viewed standing upright.

17 [0039] "User's dorsal-ventral axis" means back to front, that is, with a human user's
18 face in front; such axis is approximately horizontal when an upright human user is
19 viewed. Also sometimes referred to as front and rear.

20 [0040] "User's cheek pathway", sometimes abbreviated to "cheek pathway" or
21 "cheek path", means the pathway, traversing in either direction, from (1) outside the
22 user's mouth, (2) between such user's lips, (3) between such user's inner cheek wall
23 and the cheek-adjacent side of such user's dental arches, gums and teeth, and (4) at
24 least around the cheek-side rear tooth corner of such user's rear-most tooth or teeth
25 from cheek side to dorsal side of such tooth. The cheek pathway can be further
26 extended (5) from the user's cheek-side rear tooth corner through such user's rear-jaw
27 gap, and yet further extended (6) from such user's rear-jaw gap over such user's
28 tongue into the airspace in such user's rear-mouth cavity. The cheek pathway avoids
29 the biting (occlusal) surfaces of a user's teeth.

30 [0041] "User's cheek pouch" lies between the inner wall of one of such user's two
31 cheeks and the cheek-adjacent side of such user's dental arches, gums and teeth. A
32 user's cheek pouch extends along such user's anterior-posterior ("vertical") body axis

between the junctures of such user's mandibular and maxillary dental arches with such user's inner cheek wall. Such cheek pouch extends along such user's dorsal-ventral body axis approximately from a user's front teeth to the general area of such user's most-dorsal teeth and rear-jaw gap. The configuration of a user's cheek pouch dynamically alters as the user's jaws and lips open and close. A user has two cheek pouches located on opposing sides of a user's mouth.

[0042] "User's cheek-side position" means a location adjacent to a user's inner cheek wall, within the user's cheek pouch, in which a device can be placed.

[0043] "User's rear-jaw gap" or "rear-jaw space" means the space remaining open between such user's mandible (lower jaw) and maxilla (upper jaw) dorsally of such user's rear-most tooth or teeth when such user's jaws are closed. The size and shape of the rear-jaw gap will vary from person to person. It is sufficiently large in some persons to accommodate a cheek path airway. Sometimes the rear-jaw gap has been enlarged by extraction of at least one of the person's wisdom teeth. A user's rear-jaw gap also can be artificially enlarged by dental devices which partially block the user's bite and prevent complete closure of the user's jaws. A user generally will have two rear-jaw gaps, one on each side of the user's head.

[0044] "Air" as used herein includes any gasses or other fluids for inhalation and exhalation by humans or other creatures. "Air" could include natural environmental air at atmospheric or other pressure and partially or wholly modified gasses and fluids such as supplemental oxygen, mixtures of gasses, aerosols, and oxygenated fluids, whether or not at atmospheric pressure. It is conceived that the cheek path airway could conduct fluids other than "air", including without limitation, pharmaceutical and anesthetic gasses.

THE PROBLEMS ADDRESSED BY THE INVENTION.

[0045] Nasal air way restriction causes a variety of adverse effects, ranging from the merely uncomfortable to life threatening. The mouth provides an alternate, natural breathing airway, but not when a person's lips are closed.

[0046] Many airway devices use a mouth pathway to bypass restricted nasal passages. All airways which use a mouth pathway must be stabilized in the mouth to mitigate risks of gagging and choking and to prevent ejection from the mouth or displacement within the mouth. These problems of stable positioning of a mouth

1 airway are particularly critical while a user is asleep or otherwise is unconscious. The
2 instant invention mitigates stability problems of stand-alone cheek-side airways. It also
3 mitigates blockage of air flow openings.

4 [0047] All mouth airway devices must use materials which are essentially non-toxic
5 to the user, and the instant invention is intended to do so.

6 [0048] Most mouth airway devices are "central mouth" airways which pass between
7 the biting surfaces of a user's teeth. Such devices thus must use some form of bite
8 block to prevent closing of the user's jaws and teeth from crushing the airway. The
9 instant invention can function with or without a bite block in place.

10 [0049] Many central airway devices are anchored by dental devices that engage the
11 user's teeth or dental arches or palate. Such devices create a potential for undesired
12 orthodontic effects from the airway anchoring and from bite blocking. One
13 orthopedic/orthodontic device is designed to be installed within a user's maxillary
14 dental arch to actively modify a user's mouth anatomy, and it also includes a "pressure
15 equalization conduit" which is positioned in a cheek pathway. Pope et al., U.S. Patent
16 4,553,549. Use of dental anchoring adds complexity and expense to a cheek path
17 airway device and tends to encumber a user's jaw and tongue movements. It is
18 desirable to have a mouth airway which by-passes, and is not anchored to, a user's
19 teeth or palate.

20 [0050] The airway of the instant invention bypasses, and is not anchored to, a user's
21 teeth or palate. It avoids the more-mobile ventral portions of a user's tongue and
22 enables the more dorsal portions of a user's tongue to press the airway into positions
23 of lesser interference with the tongue's movements in the user's rear-mouth cavity.

24 [0051] It can be desirable to preserve some nasal breathing even when nasal
25 passages are restricted. Nasal passages provide a variety of desirable natural
26 breathing features such as filtering, warming and moisturizing the air, and avoidance
27 of high volumes of air flow past teeth, gums and tongue. It also is desirable to have a
28 mouth airway which allows the user's lips to nearly seal about it so as to route air
29 through the airway and avoid open-mouth breathing. Full open mouth breathing
30 causes "dry mouth" discomfort. Because the open mouth provides such a large
31 pathway, open mouth breathing tends to nearly pre-empt nasal breathing, especially if
32 the nasal passages are restricted. Some mouth airway devices aim to function as a

1 complete alternative to nasal breathing while avoiding full open-mouth breathing. For
2 example, Nelson's tube is designed so that "the flow of air therefrom will be
3 approximate to that flow of air as could be expected from normal nasal breathing," (
4 Nelson, U.S. Patent 4,170,230, Abstract).

5 [0052] The instant invention is designed to supplement, but not necessarily to
6 replace, nasal breathing. It thus can help preserve some nasal breathing. It can
7 function during periods of restricted nasal breathing before a user has switched from
8 closed-mouth nasal breathing to open-mouth breathing.

9 [0053] Problems with Cheek-side Positioning of Airways.

10 [0054] Some mouth airways, herein called "cheek-side" airways, are designed for
11 placement between the inner wall of a user's cheek and a user's cheek-adjacent gums
12 and teeth in order to avoid the biting surfaces of a user's teeth and the user's tongue.
13 This "cheek-side" location is only a portion of what is defined in this disclosure as a full
14 "cheek pathway". The Nelson airways, U.S. Patents No. 4,170,230, (1979),
15 4,261,354 (1981), 4,262,666 (1981) and 4,289,127 (1981), for example, are designed
16 to lie in a cheek-side position.

17 [0055] Cheek-side Air-flow Openings Subject to Blockage and Saliva Drainage. Air-
18 flow openings placed in a cheek-side position are subject to blockage by the user's
19 cheek, gum and tooth tissues and by mouth liquids. They also tend to drain liquids
20 into the airway tube and out of the user's mouth. As a result, there is a relatively small
21 margin for error in cheek-side positioning of air flow openings.

22 [0056] A user's inner cheek wall naturally, resiliently drapes over the cheek-adjacent
23 side of a user's dental arches, teeth and gums. It will tend to drape over an airway
24 device in a cheek-side position, urging the airway against the user's dental arches,
25 gums and teeth. This draping effect can cause blockage of cheek-side air flow
26 openings by the user's tissues, but the draping effect also provides forces that can be
27 utilized to stabilize cheek-side devices.

28 [0057] The instant invention mitigates blockage of air flow openings by curving the
29 cheek path airway around the user's rear-tooth corner from cheek side to dorsal side.
30 This curve either exposes the airway's internal open tip to the user's rear-jaw gap, or,
31 preferably, enables projection of the airway's internal open tip through the user's rear-
32 jaw gap and over the user's tongue within the airspace in the user's rear-mouth cavity.

1 The larger airspace volume within a user's rear-mouth cavity provides a larger margin
2 of error in placement of air flow openings than does a cheek-side positioning of air flow
3 openings adjacent to a user's teeth and gums. This positioning also tends to mitigate
4 exposure of the tube opening to saliva and other mouth liquids.

5 [0058] Slippage and Rotation Problems of Cheek-side Airways.

6 [0059] Cheek-side airways have numerous modes of potentially undesirable motion,
7 including the three axes of translational motions (anterior-posterior, dorsal-ventral, and
8 side-to-side or "lateral"), as well as the three modes of rotational motion (roll, pitch and
9 yaw).

10 [0060] Undesirable motions of a cheek-side airway include: slippage of the device
11 between the biting surfaces of a user's teeth; interference with the user's tongue
12 motions; slippage into gagging or choking positions; dorsal-ventral slippage of the
13 device between the user's lips, and expulsion from the user's mouth.

14 [0061] In Nelson's tubes, for example, undesirable rotation of the tube caused
15 blockage of air openings by the user's mouth tissues. Nelson's tubes also were
16 subject to dorsal-ventral slippage. Nelson, U.S. Patent 4,289,127, col. 1:35-45.

17 Nelson developed cheek-side stabilizing devices to mitigate undesirable rotational
18 motions (see particularly U.S. Patent 4,289,127), as well as to prevent dorsal-ventral
19 slippage and impairment of the user's lip seal (see U.S. Patents 4,170,230, 4,261,354,
20 4,262,666, 4,275,725, and 4,289,127).

21 [0062] Fixed-span cheek-side stabilizing devices, such as the fin-like, wire-like and
22 rod devices of Nelson, have a potentially disabling instability problem. Such fixed-
23 span devices cannot dynamically adjust to maintain a span across the gap (inter
24 occlusal space) created between a user's maxillary and mandibular teeth as the user's
25 jaws open. However, a user's jaws sometimes can open beyond that fixed-span
26 height, allowing the fixed-span device to rotate or slip between the biting (occlusal)
27 surfaces of the user's teeth.

28 [0063] Suppose, by way of hypothetical illustrative example, that the heights of a
29 user's mandibular and maxillary dental arches are 1.75 cm each (measured from their
30 respective junctures with the user's inner cheek wall to the biting surfaces of their
31 respective teeth). The vertical height of such user's cheek pocket, when the user's
32 jaws are closed, is the sum of the heights of the user's dental arches, that is, 3.5 cm.

1 The height of the user's cheek pocket with jaws closed establishes the maximum
2 vertical span of a fixed-span cheek-side stabilizing device because a greater fixed
3 span would block full closure of the user's jaws. Whenever the user is capable of
4 opening an inter occlusal space which exceeds the 1.75 cm height of one of the user's
5 dental arches then the potential will exist for a fixed-span cheek-side stabilizing device
6 to rotate or translate between the biting surfaces of such user's teeth. Suppose the
7 user's jaws open an inter occlusal space of 2 cm. Then the sum of that 2 cm inter
8 occlusal space and the 1.75 cm height of one dental arch will total 3.75 cm, which
9 exceeds the 3.5 cm maximum fixed span of a cheek-side stabilizing device that would
10 permit that user's jaws to fully close, thereby potentially permitting a fixed-span
11 stabilizing device to slip or rotate into that 2.0 cm inter occlusal space. Such an inter
12 occlusal space might occur, for example, during a yawn or a cough. Of course, the
13 hypothetical dimensions used above would vary from user to user, but the principle
14 should apply to many potential users.

15 [0064] The instant invention's solution to the instability problem of fixed-span cheek-
16 side positioning devices is to use a spring which resiliently expands and compresses
17 within the user's cheek pouch as the user's jaws open and close. The expansion of
18 the resilient cheek pouch anchor of the instant invention when a user's jaws open can
19 usefully increase the stability of a cheek-side airway over that of a fixed-span cheek-
20 side stabilizing device even if the resilient device is unable to expand the full vertical
21 height of a user's maximum jaw opening. This is because most jaw openings are less
22 than the maximum potential jaw opening.

23 [0065] Lip-Sealing Problems.

24 [0066] Cheek-side airway tubes pass between a user's lips and thus can break the
25 seal of the user's lips, permitting air passage around rather than through the tube.
26 This lip sealing problem tends to increase with increasing tube diameter and certain
27 variant shapes. There are many prior art lip-sealing devices.

28 [0067] Mouth-Corner Flanges. Nelson's patents, and especially U.S. Patents
29 4,170,230 and 4,275,725, disclose modifications of Nelson's tube by flanges which
30 engage the corner of a user's mouth and the user's lips for purposes of stabilizing the
31 tube and sealing the user's lips.

32 [0068] Lip-conforming Tube Shapes. It is known that use of a tube lip portion which

1 has an oval or somewhat flattened radial cross-section can improve sealing of the
2 user's lips. That known solution can be employed in the instant invention.

3 OBJECTIVES AND FEATURES OF THE INVENTION.

4 [0069] Objectives of this invention include the following:

5 [0070] An objective of this invention is to provide a relatively stable, supplemental
6 ventilation pathway through a user's closed lips to the rear of the user's oral cavity
7 which will remain open during closed-mouth, nasal breathing.

8 [0071] An objective of this invention is to provide supplemental air to a user's throat
9 when a user's lips otherwise remain closed for the purpose of mitigating adverse
10 effects of restricted nasal airways without requiring that the user switch from closed-
11 mouth nasal breathing to open-mouth breathing.

12 [0072] An objective of this invention is to provide an airway passing from external air
13 through a user's otherwise-closed lips to the rear of the user's oral cavity, while by-
14 passing the user's jaws, tooth biting surfaces, and much of the user's tongue, including
15 the more mobile forward portions of the user's tongue. In particular, it is an objective
16 of this invention to provide an airway which can stabilize itself within in a user's cheek
17 pathway without anchoring to a user's teeth, thus permitting opening and closing of the
18 user's jaws without disruption of the airway's cheek pathway positioning.

19 [0073] An objective of this invention is that it not physically prevent or restrict a user
20 from switching from closed-mouth nasal breathing to open-mouth breathing.

21 [0074] It is an objective of this invention that it provide one or more passive air ways
22 past closed lips which will remain relatively stable in a sleeping person,
23 notwithstanding lip, jaw and tongue motions.

24 [0075] It is an objective of this invention that it have a shape and be positioned so as
25 to minimize gagging or choking risk to a user of this invention, particularly while
26 sleeping.

27 [0076] It is an objective of this invention that it remain relatively resistant to blockage
28 of air flow openings by the cheek wall, gums, teeth, tongue or other tissue in a user's
29 mouth.

30 [0077] It is an objective of this invention that it be capable of being placed so that it
31 minimizes transmission of saliva or other mouth liquids through the airway past a
32 user's lips.

1 [0078] It is an objective of this invention that it mitigate the "dry mouth" distress
2 which many persons experience with open-mouth breathing by supplementing and
3 preserving closed-mouth nasal breathing. It is an objective of this invention to deliver
4 supplemental air directly to the rear of a user's oral cavity with a user's lips otherwise
5 closed, minimizing air currents in more ventral portions of a user's mouth.

6 [0079] It is an objective of this invention that lay persons be capable of inserting,
7 adjusting, using, and removing it by themselves.

8 [0080] It is an objective of this invention that it be adjustable to fit a particular user's
9 comfort.

10 [0081] It is an objective of this invention that it be sanitizable by the same processes
11 used for ordinary household eating utensils, such as dishwashing machines, or by the
12 processes used for artificial dentures.

13 [0082] It is an objective of this invention to provide a supplemental air way to the rear
14 of a user's mouth cavity which can function in combination with devices designed to
15 control a user's tongue, tooth and/or jaw position, so the combination can
16 cooperatively mitigate impaired breathing due to restriction of the user's nasal and
17 throat airways. It also is an objective that the airway be compatible, and function in
18 combination, with an anti-bruxing dental device. One useful effect, where such jaw-
19 control or anti-bruxing devices block full closing of a user's jaws, is that such devices
20 can increase the cross-sectional area of a user's rear-jaw gaps which thereby more
21 easily accommodate a larger diameter cheek path airway.

22 [0083] Jaw-control and Tongue-Control Devices.

23 [0084] Examples of existing intra-oral, jaw-control and tongue-control devices with
24 which it is conceived the invention might be used in combination (perhaps requiring
25 some modification) are:

26 Fenton, U.S. Pat. No. 5,499,633; Halstrom, U.S. Pat. No. 5, 868,138; Strong, U.S. Pat.
27 No. 6,418,933; Thornton, U.S. Pat. No. 6325,064 B1; Meade, U.S. 6,055,986; Belfer,
28 U.S. Pat. No. 6,092,523; Frantz, U.S. Pat. No. 6,109,625; Bergersen, U.S. Pat. No.
29 6,129,084; Thornton, U.S. Pat. No. 6,155,262; David, U.S. No. 6,450,167 B1;
30 Tielmans, U.S. Pub. No. 2001, 0027793 A1 and U.S. Pat. No. 6,408,852 B2; Gaskell,
31 U.S. Pub. No. 2002/0000230 A1; and Dort, Pub. No. US 2002/0117178 A1 (Aug.
32 2002). See also Thornton, U.S. Pat. No. 6,209,542 (nasal mask combined with dental

device). Wagner, U.S. Patent 5,566,684 (1996) discloses a mouthguard which a user can self-fit to the user's maxillary dentition to mitigate nocturnal teeth grinding. An embodiment of Wagner's device, with instructions for self-fitting by users, is marketed under the trade name "The Doctor's Night Guard", by Dental Concepts, Paramus, N.J., USA. There are advantages where a cheek-path airway is physically separated from the jaw-control and tongue-control devices, but designed to be used in a user's mouth in combination with such devices. The cheek-path airway then can be inserted or removed separately from the jaw- or tongue-control device, enabling separate handling of the cheek-path airway and such devices, such as separate fitting, adjustment, cleaning, and replacement. Moreover, it is conceived that existing jaw- and tongue-control devices which do include built-in airways could be simplified, and thus more readily constructed, if such built-in airways are deleted and their function replaced by a physically separate cheek-path airway adapted for combination use with such modified devices.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS.

[0085] Figure 1 is an elevation view of a cheek path airway combined with a cheek pouch anchor.

[0086] Figure 2 is an elevation view of the same cheek path airway combined with a cheek pouch anchor, as is Figure 1, but folded.

[0087] Figure 3 is an elevation view of the side of a user's face showing a section view of the user's mouth, along Section 3-3 of Figure 3A, with the user's cheek removed, showing placement of a cheek path airway combined with a cheek pouch anchor.

[0088] Figure 4 is a section view, along section 4-4 of Figure 4A, looking upward at the user's maxillary teeth and jaw with cheek path airways in place.

[0089] Figure 5 is a perspective view of a cheek path airway and cheek pouch anchor approximately positioned relative to a dental device.

[0090] Figure 6 is a perspective view of a dual cheek path airway folded into the approximate shape for placement in a user's cheek pathways.

[0091] Figure 7 is a view of the same dual cheek path airway as in Figure 6, but showing the airway in-line, with a zero curvature along its longitudinal axis, as manufactured but before folding the airway to fit a user's mouth.

[0092] Figure 8 is a perspective view of a dual cheek path airway placed in cheek pathways in a user's mouth.

[0093] Figure 9 is a second perspective view of a dual cheek path airway placed in cheek pathways in a user's mouth.

[0094] Figure 10 is an elevation view of a user's face showing external airway stabilizing devices in place.

[0095] Figure 11 is a perspective view of a user's face with mouth open, showing a dual cheek path airway with external stabilizing extensions in place.

[0096] Figure 12 is a perspective view, from the upper left front, of a dual cheek path airway approximately positioned about an inverted (upside down), articulated, dental jaw-control device.

[0097] Figure 13 is a perspective view, from the upper rear, of an articulated, prior art, dental jaw-control device.

[0098] Figure 14 is a plan view of an inverted (upside down) dental jaw-control device with two single-cheek versions of the airway approximately positioned about it.

[0099] Figure 15 is an elevation view of the side of a user's face, showing a section view along section 15 - 15 of Figure 15A with the user's cheek removed, and showing a cheek path airway placed about a dental jaw-control device in the user's mouth.

Table of Drawing Elements

[0100]	Cheek Path Airway Elements	
[0101]	1	external open tip of hollow tube, to be positioned external to user's lips
[0102]	1a	external open tip on second end of hollow tube in dual-cheek version of airway
[0103]	2	lip portion of hollow tube, for traversing between user's lips
[0104]	2a	second lip portion of hollow tube in dual-cheek version of airway
[0105]	3	cheek-side portion of hollow tube, to be positioned between inner side of user's cheek and cheek-adjacent (buccal) side of user's teeth and gums
[0106]	3a	second cheek-side portion of hollow tube in dual-cheek version of airway
[0107]	4	rear-tooth corner portion of hollow tube; curved, or flexible, transition from cheek-side portion to jaw-gap portion of hollow tube, adjacent to rear-most tooth.

- 1 [0108] 4a rear-tooth corner portion, curved, or flexible, transitioning from cheek
2 portion to jaw-gap portion of hollow tube, adjacent to rear-most tooth in
3 dual cheek version of airway.
- 4 [0109] 5 rear-jaw gap portion of hollow tube (may be straight, or curved, or
5 flexible)
- 6 [0110] 5a Second rear-jaw gap portion of hollow tube in dual cheek version of
7 airway.
- 8 [0111] 6 Tongue portion of hollow tube, to extend from rear-jaw gap over user's
9 tongue into user's rear mouth cavity (may be straight, or curved, or
10 flexible).
- 11 [0112] 6a Second tongue portion of hollow tube in dual cheek version of airway.
- 12 [0113] 7 Rear-mouth cavity-spanning portion of hollow tube in dual cheek version
13 of airway; joins first and second cheek-side portions 8 and 9 of dual
14 cheek version.
- 15 [0114] 8 First cheek-side portion of hollow tube in dual cheek version of airway, to
16 traverse user's first cheek pathway on first side of user's mouth
- 17 [0115] 9 Second cheek-side portion of hollow tube in dual cheek version of
18 airway, to traverse user's second cheek pathway on second side of
19 user's mouth.
- 20 [0116] 10 air flow opening in first position in wall of external end of hollow tube
- 21 [0117] 10a air flow opening in first position in wall of second external end of hollow
22 tube in dual cheek version
- 23 [0118] 11 air flow opening in second position in wall of external end of hollow tube
- 24 [0119] 11a air flow opening in second position in tube wall of second external end of
25 hollow tube in dual cheek version.
- 26 [0120] 12 air flow opening in first position in tube wall of tongue portion of hollow
27 tube (tube portion 6)
- 28 [0121] 12a air flow opening in first position in tube wall of second tongue portion of
29 hollow tube (tube portion 6a) in dual cheek version
- 30 [0122] 13 Air flow opening in second position in tube wall of tongue portion of
31 hollow tube.
- 32 [0123] 13a Air flow opening in second position in tube wall of second tongue portion

1 of hollow tube in dual cheek version.
 2 [0124] 14 Air flow opening in third position in tube wall of tongue portion near the
 3 center of the rear-mouth cavity in single cheek version of airway;
 4 alternately, located in hollow tube portion 7 in dual cheek version of
 5 airway.
 6 [0125] 15 Air flow opening in wall of hollow tube, in fourth position in tongue portion
 7 of hollow tube near the center of the rear-mouth cavity in single cheek
 8 version of airway; alternately, located in hollow tube portion 7 in dual
 9 cheek version of airway.
 10 [0126] 16 internal open end of hollow tube, located on tongue portion of hollow
 11 tube in single cheek version of airway, to be projected within airspace in
 12 user's rear-mouth cavity.
 13 [0127] 16a internal open end of second hollow tube, located on second
 14 tongue portion of second hollow tube in user's second cheek
 15 pathway, when two single cheek versions used in opposite
 16 cheeks.
 17 [0128] 17 lacing holes in cheek-side portion of hollow tube, adapted to receive
 18 flexible, resilient filament 28 of cheek positioning device.
 19 [0129] 18 reserved
 20 [0130] 19 reserved
 21
 22 [0131] Airway Retainer Elements
 23 [0132] 20 a first type of retainer on external end of hollow tube
 24 [0133] 21 reserved
 25 [0134] 22 a second type of retainer, mouth-corner portion of hollow tube, to curve
 26 from lip portion 2 of tube about corner of user's mouth to outside wall of
 27 user's cheek
 28 [0135] 23 External cheek-side extension of hollow tube.
 29 [0136] 24 Flexible (or curved) portion of external cheek-side extension of tube
 30 [0137] 25 Flexible (or curved) ear piece of external extension of tube
 31 [0138] 26 Finger grip portion of ear piece.
 32 [0139] 27 Tape site on external cheek-side extension of hollow tube, for taping tube

1 to user's face.

2

3 [0140] Cheek Pouch Anchor Elements

4 [0141] 28 Flexible, resilient filament

5 [0142] 28a First (upper) loop in laced filament

6 [0143] 28b second (upper) loop in laced filament

7 [0144] 28c third (lower) loop in laced filament

8 [0145] 28d fourth (lower) loop in laced filament

9 [0146] 29 First curled (or crimped) end of filament

10 [0147] 29a Second curled (or crimped) end of filament

11

12 [0148] User's Body Parts

13 [0149] 30 user's upper lip

14 [0150] 31 user's lower lip

15 [0151] 32 inner wall of user's first cheek

16 [0152] 32a inner wall of user's second cheek

17 [0153] 33 user's upper (maxillary) rear-most (dorsal) tooth on first side of user's

18 mouth

19 [0154] 33a user's upper (maxillary) rear-most (dorsal) tooth on second side of user's

20 mouth

21 [0155] 34 lingual (tongue) side of user's rear-most upper (maxillary) tooth on first

22 side of user's mouth

23 [0156] 34a lingual (tongue) side of user's rear-most upper (maxillary) tooth on

24 second side of user's mouth

25 [0157] 35 buccal (cheek-adjacent) side of user's rear-most upper (maxillary) tooth

26 on first side of user's mouth

27 [0158] 35a buccal (cheek-adjacent) side of user's rear-most upper (maxillary) tooth

28 on second side of user's mouth

29 [0159] 36 user's upper jaw (maxilla) on first side of user's mouth

30 [0160] 36a user's upper jaw (maxilla) on second side of user's mouth

31 [0161] 37 user's lower jaw (mandible) on first side of user's mouth

32 [0162] 38 user's rear-most (dorsal) lower (mandibular) tooth on first side of user's

1 mouth.

2 [0163] 39 user's tongue

3 [0164] 40 roof of user's rear-mouth (oral) cavity

4 [0165] 41 airspace in user's rear-mouth (oral) cavity

5 [0166] 42 user's rear-jaw gap on first side of user's mouth

6 [0167] 42a user's rear-jaw gap on second side of user's mouth

7 [0168] 43 Occlusal (biting) surface of user's tooth.

8 [0169] 44 User's uvula (depending from user's soft palate)

9 [0170] 45 First corner of user's mouth (at juncture of upper and lower lips).

10 [0171] 45a Second corner of user's mouth.

11 [0172] 46 External wall of user's first cheek

12 [0173] 47 User's first ear

13 [0174] 48 Lower side of user's first ear

14 [0175] 49 Upper side of user's first ear

15 [0176] 50 Dotted approximate outline of user's cheek pouch (showed with user's

16 cheek removed)

17

18 [0177] Dental Device Elements

19 [0178] 51 upper (maxillary) portion of dental device (showed upside down in some

20 drawings)

21 [0179] 52 lower (mandibular) portion of dental device (showed upside down in

22 some drawings)

23 [0180] 53 female (or sleeve) portion of adjustable strut of dental device

24 [0181] 54 male (or arm) portion of adjustable strut of dental device

25 [0182] 55 pivot bolt for mounting adjustable strut in maxillary portion of dental

26 device

27 [0183] 56 pivot bolt for mounting adjustable strut in mandibular portion of dental

28 device

29 [0184] 57 collar of male (arm) portion of adjustable strut of dental device

30 [0185] 58 collar of female (sleeve) portion of adjustable strut of dental device

31 [0186] 59 wire reinforcing frame embedded in lower (mandibular) portion of dental

32 device.

1 [0187] 60 wire reinforcing frame embedded in upper (maxillary) portion of dental
2 device.
3 [0188] 61 series of teeth-engaging balls mounted on wire reinforcing frame 33 and
4 projecting out of body of mandibular portion of dental device
5 [0189] 62 channel fitted to user's mandibular teeth
6 [0190] 63 channel fitted to user's maxillary teeth
7 [0191] 64 dental device, with channel fitted to user's teeth

8 DETAILED DESCRIPTION OF THE INVENTION

9 [0192] Figure 1 shows a cheek path airway combined with a cheek pouch anchor.
10 The cheek path airway is formed of a hollow tube (showed as manufactured in-line,
11 with approximately zero curvature along its longitudinal axis), having external open tip
12 1, lip portion 2, cheek-side portion 3, flexible rear-tooth corner portion 4, rear-jaw gap
13 portion 5, tongue portion 6, air flow openings 10 and 11 in the tube wall placed
14 adjacent to external open tip 1, and air flow openings 14 and 15 in the tube wall placed
15 adjacent to internal open tip 16, with lacing holes 17 through the walls of the cheek-
16 side portion 3 of the hollow tube. Figure 1 also shows flexible, resilient filament 28,
17 slidably laced through lacing holes 17 of the hollow tube, to form upper first loop 28a,
18 upper second loop 28b bearing upper curled loop end 29, lower third loop 28c, and
19 lower fourth loop 28d bearing lower curled loop end 29a. Loops 28a, 28b, 28c and
20 28d combine to form the whole loop span formed by the flexible, resilient filament 28.
21 By tugging on curled loop ends 29 and 29a a user can lengthen loops 28b and 28d
22 and shorten loops 28a and 28c; conversely, by tugging on loops 28a and 28c a user
23 can lengthen those loops while shortening loops 28b and 28d, thus enabling a user to
24 adjust the whole loop span of filament 28 for better fit.

25 [0193] Figure 2 shows the same cheek path airway combined with a cheek pouch
26 anchor as in Figure 1, but with the flexible rear tooth-corner portion 4 folded for
27 positioning in a user's cheek pathway.

28 [0194] Figure 3 depicts a cheek path airway combined with a cheek pouch anchor
29 and placed in a user's cheek pathway and cheek pouch. Figure 3 shows the hollow
30 tube airway with external open end 1 in a position outside the user's lips, and lip
31 portion 2 passing between the user's upper lip 30 and lower lip 31. Figure 3 shows
32 cheek-side portion 3 of the hollow tube lying adjacent to the buccal side of the user's

1 teeth, with rear-tooth corner portion 4 of the hollow tube flexed about the user's rear-
2 most (dorsal) upper tooth 33 and lower tooth 38. It shows airway rear-jaw gap portion
3 5 passing through user's jaw gap 42, adjacent to user's tongue 39. It shows flexible,
4 resilient filament 28 laced through lacing holes 17 in cheek-side portion 3 of the hollow
5 tube, and placed within the user's cheek pouch which is approximately outlined by the
6 dotted line 50.

7 [0195] Figure 4 depicts a section view, along section 4-4 of Figure 4A, looking
8 upward at a user's upper (maxillary) jaw and teeth. It shows two variants of the single-
9 cheek version of the airway placed in the user's two cheek pathways on opposing
10 sides of a user's mouth. In the user's first cheek pathway, in the lower part of the
11 drawing, the hollow tube has external open end 1, with added mouth-corner portion 22
12 flexed to curve about the corner of the user's mouth to act as a retainer element,
13 external cheek-side portion 23 bearing a tape site 27 for taping the tube to a user's
14 cheek, and air flow opening 11. Lip portion 2 of the hollow tube passes the user's
15 upper lip 30, cheek-side portion 3 passes between the user's inner cheek wall 32 and
16 the buccal side of the user's teeth and gums, with rear-tooth corner portion 4 of the
17 hollow tube flexed about the user's rear-most (dorsal), upper (maxillary) tooth 33,
18 which tooth has a lingual side 34. Rear-jaw gap portion 5 of the hollow tube passes
19 user's upper jaw (maxilla) 36 through the user's rear-jaw gap 42. Tongue section 6 of
20 the hollow tube projects internal open end 16 of the hollow tube into the airspace 41 in
21 the user's rear-mouth cavity. Adjacent to internal open end 16 is air flow opening 14 in
22 the wall of the hollow tube. The upper portion of Figure 4 shows the user's second
23 cheek pathway with a second airway in place. The second airway is modified with
24 retainer 20 placed adjacent to the external open tip 1a, positioned outside of user's
25 upper lip 30.

26 [0196] Figure 5 depicts a cheek path airway approximately positioned about a dental
27 device 64 which has a channel 62 to engage a user's lower teeth (or 63 if engaging
28 user's upper teeth). The dental device 64 can be used to expand a user's rear-jaw
29 gap, while also performing other functions such as an anti-bruxing device.

30 [0197] Figures 6 and 7 are comparative depictions of the same dual cheek path
31 airway, except that in Figure 7 the airway's longitudinal axis has approximately zero
32 curvature, as manufactured in-line. By comparison, in Figure 6 the airway has been

1 folded after manufacture to approximate the shape necessary to fit into the cheek
2 pathways in a user's mouth. Figures 6 and 7 show a hollow tube having external open
3 end 1 and adjacent air flow openings 10 and 11 in the tube wall; lip portion 2; cheek-
4 side portion 3; rear-tooth corner portion 4; rear-jaw gap portion 5; tongue portion 6 with
5 flexible joints and with air flow opening 12 in the tube wall; and rear-mouth-cavity
6 spanning portion 7 with air flow opening 15 in the tube wall. In the dual cheek path
7 airway the rear-mouth-cavity spanning portion 7 joins first cheek-side portion 8
8 (comprised of portions 1 through 6) with second cheek-side portion 9 (comprised of
9 portions 1a through 6a).

10 [0198] Figure 8 depicts a user's gaping mouth with a dual cheek path airway
11 approximately placed. The view looks at a slight upward angle towards the user's
12 upper teeth including rear-most tooth 33 having lingual side 34 and buccal side 35 with
13 rear-tooth corner portion 4 curved about rear-most tooth 33. Figure 8 depicts rear-jaw
14 portion 5 of the airway passing through the user's rear-jaw gap 42. It also depicts
15 airway portions 6 and 7, with air flow openings 12 and 14 positioned above the user's
16 tongue 39, in the airspace 41 of the user's rear-mouth cavity adjacent the roof 40 of
17 the user's mouth, ventrally of the user's uvula 44. The depicted placement of the
18 cheek path airway is somewhat distorted, relative to the user's mouth parts, from
19 where the airway would typically lie when the user's mouth is in a less gaping position.

20 [0199] Figure 9 is the same as Figure 8 except that the view is at a slightly more
21 downward angle enabling a view of the user's lower teeth and a less obstructed view
22 of the rear of the user's mouth, including uvula 44. This view also somewhat distorts
23 the positioning which the airway would have relative to the user's mouth parts if the
24 user's mouth were in a less gaping posture.

25 [0200] Figure 10 shows a front and side perspective view of a user's face with a dual
26 cheek path airway in place and the user's lips closed. The airway projects out through
27 the user's lips, near the corners 45 and 45a of the user's mouth, with external air flow
28 opening 10 adjacent to the user's lips. The second type of retainer, mouth-corner
29 portion 22 of the hollow tube, curves about the corner 45 of the user's mouth. External
30 cheek-side extension 23, having flexible joint portion 24, lies along the outside of the
31 user's cheek 46. Flexible ear piece 25 is curved about the lower side 48 and the upper
32 side 49 of the user's ear 47, and the airway's ear piece 25 terminates in finger grip

1 portion 26.

2 [0201] Figure 11 depicts a user's face and open mouth with a dual cheek airway in
3 place, where the airway has external stabilizing parts, including mouth-corner portion
4 22, external cheek-side extension 23 with flexible joint 24, and ear piece 25 with finger
5 grip portion 26.

6 [0202] Figure 12 depicts a frontal and side perspective view of a dual cheek path
7 airway folded about a dental jaw-control device in a very rough approximation of the
8 relationship that the airway would have to the dental device in a user's mouth, with the
9 airway passing behind the dental device and around the outside of the struts of the
10 dental device. For convenience the dental device is depicted upside down and is
11 articulated to better display its parts. The dental device has a mandibular (lower jaw)
12 portion 52 and a maxillary (upper jaw) portion 51, which are connected by adjustable
13 struts on either side. The struts have female (sleeve) portion 53 which slidably receives
14 male (arm) portion 54. The struts have collars 57 and 58 which are rotatably mounted
15 on pivot bolts 55 and 56. Pivot bolt 55 is rigidly mounted near the dorsal end of
16 maxillary portion 51, and pivot bolt 56 is rigidly mounted near the ventral end of
17 mandibular portion 52. Mandibular portion 52 and maxillary portion 51 typically are
18 formed of plastic cast in molds imprinted by a user's mandibular and maxillary teeth.
19 Wire reinforcing frames 59 and 60, as well as seats for pivot bolts 55 and 56, are
20 embedded in the plastic casts which form mandibular portion 52 and maxillary portion
21 51. The embedded reinforcing wire frames 59 and 60 are visible because the plastic in
22 which they are embedded is clear. Figure 12 depicts the dual cheek path airway with
23 flexible rear-tooth corner portion 4 of the airway folded to project cheek-side portion 3
24 around the outside of the strut of the dental device, and to project rear-jaw-gap portion
25 5 of the airway about the dorsal corner of the dental device. Flexible joints in tongue
26 portion 6 and rear-mouth-cavity spanning portion 7 of the airway curve about the dorsal
27 side of the dental device.

28 [0203] Figure 13 depicts from a dorsal perspective the same dental jaw-control device
29 as that depicted in Figures 12 and 13 in combination with cheek path airways. The
30 dental device is depicted upside down to expose the teeth-engaging channel 62 of
31 mandibular portion 52 which is cast from a mold of a user's mandibular teeth. The
32 embedded wire reinforcing frame projects a series of teeth-engaging balls 61 out of the

1 plastic cast adjacent to the buccal wall of teeth-engaging channel 62. Figure 13 also
2 depicts another view of the wire reinforcing frame 60 embedded in the clear plastic cast
3 which forms maxillary portion 51 of the dental device. The entire dental jaw-control
4 device depicted in Figure 13 is prior art, but is depicted in order to show additional
5 aspects of the dental device with which the cheek path airway can be combined.
6 [0204] Figure 14 is a plan view depicting two single-cheek versions of the airway
7 approximately positioned about the same dental jaw-control device as is depicted in
8 Figures 12 and 13. Figure 14 shows rear-tooth corner portion 4 of the airway flexed
9 about the dorsal corner of the dental device, projecting rear-jaw gap portion 5 and
10 tongue portion 6 of the airway about the dorsal side of the dental device and projecting
11 cheek-side portion 3 around the outside of the struts of the dental device, in
12 approximately the positions which the airways would have relative to the dental device
13 when both are in place in a user's mouth with the user's jaws closed.
14 [0205] Figure 15 is a side view of a user's face, along section 15 - 15 of Figure 15A,
15 with the user's cheek removed. It shows a cheek path airway placed in a user's cheek
16 pathway so as to operate cooperatively with a dental jaw-control device which also is in
17 place in the user's mouth. Maxillary portion 51 of the dental device is engaging the
18 user's maxillary teeth and mandibular portion 52 is engaging the user's mandibular
19 teeth, with pivot bolt 56 disposed more ventrally on mandibular portion 52 and pivot bolt
20 55 disposed more dorsally on maxillary portion 51 so that the user's mandibular jaw is
21 urged ventrally relative to the user's maxillary jaw. The purpose is to prevent the user's
22 mandibular jaw from sagging dorsally towards the user's throat when the user is lying
23 more or less supine during sleep. The dental device also can serve an anti-bruxing
24 function. A cheek path airway is placed around the dental device with cheek-side
25 portion 3 of the airway positioned outside the strut (sleeve 53 and arm 54) of the dental
26 device. The rear-tooth corner portion 4 of the airway curves about the dorsal corner of
27 the dental device, and rear-jaw gap portion 5 of the airway projects dorsally of the
28 dental device. In this configuration the user can open and close the user's jaws,
29 operating the slidable sleeve 53 and arm 54 of the dental device while the collars of the
30 strut rotate about pivot bolts 55 and 56. When placed in a cheek pathway the inner wall
31 of the user's cheek (not shown in Figure 15) drapes over and presses against the
32 relatively rigid cheek-side portion 3 of the airway while the relatively rigid lip portion 2 of

1 the airway projects between the user's lips 30 and 31. Pressure of the user's inner
2 cheek wall and mouth corner (not shown in Figure 15) urges portion 3 of the airway
3 against the strut (sleeve 53 and arm 54) of the dental device, helping constrain pitch
4 and yaw rotation of the airway. Sleeve 53 and arm 54 of the dental device also prevent
5 cheek-side portion 3 of the airway from slipping laterally between the maxillary and
6 mandibular portions 51 and 52 of the dental device when the user's jaws open.

7 8 Preferred Embodiments of Invention.

9 [0206] Airway Tube. In a preferred version, the cheek path airway is formed as a
10 relatively rigid tube with flexible joints interspersed at strategic positions along the
11 tube's longitudinal axis. The more rigid sections of the tube provide structural stability
12 and better leverage to avoid the biting surfaces of a user's teeth, as well as to better
13 project the internal and external open ends of the airway into desirable locations. By
14 reference to Figures 3, 4, 8, 9, 10, 11 and 15, the user's inner cheek wall; drapes over
15 and provides cheek-side pressure upon cheek-side portion 3 which is relatively rigid
16 along the longitudinal axis. In Figures 3, 3A, 8, 9, 10, 11, 15 and 15A the user's inner
17 cheek walls are not visible and labeled but may be inferred from human anatomy. The
18 user's mouth corners 45 and 45A, labeled in Figure 10, and the user's lips 30 and 31
19 can drape about airway portions 2 and 2A as depicted in Figures 3, 8, 9, 10, 11 and 15.
20 Figure 4, a schematic, is not drawn to scale but rather exaggerates spacing between
21 the user's inner cheek walls 32 and 32A and airway cheek-side portions 3 and 3A in
22 order to more clearly delineate the airway structure from the user's mouth tissues. By
23 reference to Figure 15 the draping effect of the user's cheek (not shown) urges cheek-
24 side portion 3 against sleeve 53 and arm 54 of the strut of the dental device,
25 constraining rear-tooth corner portion 4 and rear-jaw gap portion 5 of the tube from
26 yawing into the inter occlusal space between mandibular portion 52 and maxillary
27 portion 51 of the dental device. By reference to Figure 3, the draping effect of the
28 user's cheek (not shown) presses against both rigid cheek-side portion of the airway
29 and against the cheek pouch anchor, again constraining yawing of rear-tooth corner
30 portion 4 and rear-jaw gap portion 5.

31 [0207] In-Line Manufacture of Airway Tube. The airway tube, including the flexible
32 joints, preferably is manufactured "in-line," that is, with near-zero curvature in the

longitudinal axis of the tube, as in Figures 1 and 7. Such near-zero curvature during manufacture will ease manufacture, packaging, transportation, storage and retail display of the airway, while the interspersed flexible joints enable a user to shape the tube along its longitudinal axis to fit the user's mouth, as in Figures 1, 6 and 8-11.

[0208] A modification of the instant cheek airway is designed to enable incorporation of a mouth-corner retainer element in a single, in-line manufacturing process by simply extending the length of the hollow tube with flexible joints inserted to enable the tube to fold about the corner of a user's mouth and along the outer wall of a user's cheek, depicted as element 22 in Figures 4, 10 and 11. The tube can even be manufactured in-line with sufficient length to curve about a user's ears, as element 25 in Figures 10 and 11. Adaptation of the hollow tube for in-line manufacturing is preferred to eliminate the necessity to add flanges by some additional assembly process, and has the added features of easier packing, shipping and display, while enabling the end user to fold the in-line tube for better personal fit.

[0209] Tongue-Avoiding Feature. In one preferred modification of the cheek airway invention, at least one of the rear-tooth corner portion 4, the rear-jaw gap portion 5 and the tongue portion 6 of the airway is stiffly flexible so that a user's tongue can press the airway into locations of lesser interference with the user's tongue, near the side and roof of the user's rear-mouth cavity. Not only does the resulting configuration reduce interference with the user's tongue, but also it can help retain the airway in the user's cheek pathway.

[0210] Tube Diameters Related to Rear-jaw Gap and Lip Seal. By comparison to the 2 to 3 mm inside diameter which is explicitly disclosed for the pressure-equalization conduit of Pope, et al., U.S. Patent 4,553,549, larger diameters are preferred for the instant invention, to the extent that the user's rear-jaw gap can accept such larger diameters; larger diameters enable the higher flow volumes desired for the breath-supplementation function of the instant invention. By way of non-limiting example, tube inside diameters of approximately 5.5 mm to 6.5 mm, have been used in the instant invention for an adult human. The instant invention is not specifically limited to such range of diameters, but rather it typically will be limited by the cross-sectional area of the particular user's rear-jaw gap.

[0211] Lip-sealing problems can be mitigated in the instant invention by employing a

1 smaller diameter tube around which a user's lips still can nearly seal. When using such
2 smaller diameter tubes, one accepts that the resulting lesser air flow through the cheek
3 path airway may only supplement, not entirely replace, nasal breathing. However, lip
4 sealing tends to be a less critical issue in the instant invention because the invention is
5 founded in part upon a recognition that there can be benefit to preservation of some
6 nasal air flow by using a cheek path airway merely to supplement nasal air flow rather
7 than replacing it; as a result a tube smaller than the diameter tube required to
8 completely replace nasal breathing can be employed to more readily allow the user's
9 lips to seal about the tube.

10 [0212] In many instances the maximum radial cross-section of a tube which can be
11 fitted to a user's rear-jaw gap also will be small enough to allow the a user's lips to seal
12 around the instant cheek airway tube sufficiently to render lip sealing an insignificant
13 issue. While it is desirable in the instant invention to preserve a user's normal lip seal
14 when the user is breathing nasally, the instant invention is designed to not prevent and
15 not hinder open-mouth breathing when the user's physiologic state naturally triggers a
16 switch from nasal to open-mouth breathing. When supplementing nasal air flow, the
17 instant invention does not necessarily require a strict lip seal, but it is desirable to
18 enable a user to substantially preserve the user's natural lip seal.

19 [0213] Methods of Making and Using.

20 [0214] The cheek path airway can be manufactured from plastic materials such as
21 those in use for flexible drinking straws, provided that they be essentially non-toxic. It is
22 conceived that the cheek path airway could be manufactured by modification of
23 methods and machines presently widely used for the manufacture of flexible drinking
24 straws.

25 [0215] Portions of a relatively rigid tube can be rendered flexible by imposing
26 corrugations in the tube wall similar to those which render plastic drinking straws
27 flexible. Such corrugations can render a tube somewhat extensible as well as flexible.
28 A wide variety of methods could impart the essential curves to fit a user's cheek path.
29 For example, portions of the tube could be rendered flexible by helical coils of wire or
30 filament covered by an outer sheath; or semi-rigid, simi-flexible tubing could be used
31 throughout and adjusted by hand molding to fit a cheek pathway. Materials of differing
32 flexibility could be fused or welded together. The degree of flexibility versus rigidity

1 could be altered by controlling the thickness of the tube walls and their chemical
2 composition.

3 [0216] The thickness of the walls of plastic tubes can be adjusted to enable such tube
4 walls to deform to a flattened or oval shape, which better conforms to the cross-section
5 of a particular user's rear-jaw gap, but without collapse of the hollow air passageway.
6 The deformation can be flexible or malleable, as well as resilient. For comfortable fit, it
7 is preferable that the outer surface of the rear-jaw gap portion 5 of the airway tube be
8 smooth, rather than corrugated, to minimize irritation when the jaws close the rear-jaw
9 gap to its minimum cross-section.

10 [0217] Airflow openings and filament-lacing holes can be melted through the walls of
11 plastic tubes by use of a heated pointed instrument. It is conceived that the tube walls
12 could be initially formed with such openings, or openings could be cut or stamped, or
13 formed with a focused laser beam.

14 [0218] It is conceived that in a combination of the cheek pouch anchor with the cheek
15 path airway, much of the stabilizing function can be assumed by the anchor, permitting
16 a wider range in the design of flexibility and rigidity in the tube.

17 [0219] The filament used in the cheek pouch anchor can be manufactured from
18 monofilament plastic line similar to that in common use for heavier weights of fishing
19 line, provided that it be essentially non-toxic. Flexibility and resilience can be controlled
20 by controlling the size of the cross-section of the monofilament, as well as its
21 composition. It is conceived that flexibility and resilience also could be affected by
22 changes in the shape of the monofilament's cross-section. Such monofilament line can
23 be heat-molded at relatively low temperatures into curves of the desired shapes and it
24 develops a "memory" for such a heat-molded shape which aids shaping of spring-like
25 curves in the monofilament line. Altering the locations of the lacing holes 17 in portion
26 3 of the airway tube alters the shape of the curves in the cheek pocket anchor. The
27 filament could be formed of metal or a combination of metal and plastic.

28 [0220] The cheek path airway, the cheek pouch anchor, and the combination of them,
29 can be sanitized in an ordinary household dishwasher in the same manner as dining
30 utensils, provided that temperatures in the machine are not so high as to excessively
31 soften the materials of the devices.

32 [0221] Because all parts can be formed of plastic, it is conceived that the cheek path

1 airway, and possibly the combination of the cheek path airway and cheek pouch
2 anchor, could be manufactured and assembled sufficiently inexpensively for short term
3 use and possibly to be disposable.

4 [0222] Some Definitions Used in the Claims.

5 [0223] For purposes of the claims the following words have the following meanings:

6 [0224] "Conduit" means a hollow tube or channel capable of conveying fluids
7 along its longitudinal axis, which axis may be curved. A conduit may have
8 one or more separate passageways through it and thus have a plurality of
9 longitudinal axial dimensions. The conduit's cross-section may enclosed
10 (as in a tube by way of non-limiting example), or partially open (as in an
11 open-top channel by way of non-limiting example). The conduit's radial
12 cross-section may have a single-focus radius (circular cross-section) or
13 may have multi-focal radii or variable length radii and thus have a plurality
14 of radial dimensions (oval or other variant shape which can include multi-
15 lateral shapes, that is, a plurality of sides). A conduit's radial cross-
16 section may vary along the conduit's longitudinal axis.

17 [0225] "Curve" means a geometric figure which may have any degree of
18 curvature; it may but need not include zero curvature, that is, a straight
19 line, as well as positive or negative curvature.

20 [0226] "Filament" includes at least one thread, fibre, strand, wire, line, string,
21 strip, or the like. It may include multi-strand or braided configurations.
22 The radial cross-section of the filament may, but need not necessarily be,
23 circular.

24 [0227] "Flexible" includes bendable, pliable, moldable, and adjustable.

25 [0228] "Portion" of a conduit refers to an approximate functional location or
26 position along the longitudinal axis of the conduit, without necessarily
27 implying sharp or distinct boundaries between portions and functions;
28 one portion may have an indistinct or blended joiner with another
29 portion, and when the conduit is installed in a user's mouth a portion may
30 conform only approximately to the indicated parts of a user's mouth.